

Claims 1 to 4 and 8 have been rejected under 35 USC §103 as unpatentable over Noiles, et al. ("Noiles") in view of any of Cremascoli, U.S. Patent No. 5,263,988 to Huebner or U.S. Patent No. 4,566,138 to Lewis, et al. ("Lewis"). It is submitted the rejection is improper and should be withdrawn.

Noiles discloses a prosthesis having a metal external shell and a metal bearing. The angle of the conical lock is stated as 6° to 17° at column 3, lines 12. Further, the metal bearing, also referred to as the "insert", is fashioned with recesses for engagement by a tool.

In the present invention, the anti-friction liner is of a ceramic material. The metal bearing in Noiles is not of a ceramic material since it is fashioned with a number of recesses (hub 34, etc.). The intricate machining required to form a hub with recesses as required by Huebner cannot be done with a ceramic.

In the present invention, the ceramic anti-friction liner is made without external recesses. To remove the anti-friction shell (2), at least one recess (3) is arranged in the metal shell (1) on the surface in contact with the anti-friction shell (2).

Cremascoli describes a total hip prosthesis which appears to be formed in part from a metal annular body (i.e., a ring), with a thread and a ceramic component. However, the ceramic component is coupled to the metal ring element by hot or cold casting, and is held securely in place by the high pressure which develops between the outer ceramic surfaces and inner metal surfaces after cooling of the metal annular body (see column 2, lines 1 to 5). Casting refers to pouring a molten substance into a mold to solidify to a desired shape. In Cremascoli, that part of the outer ceramic component surface not intended to be coupled to the metal ring is then coated with a single, double, or plural layer of crushed granular material (see

column 2, lines 5 to 8).

Huebner relates to a bipolar endoprosthesis and does not show or suggest a taper-lock construction. The Huebner construction requires a locking ring (10) which positions and retains the insert (9) in place. The locking ring (10) is shown in detail in Figure 5. In column 4, Huebner discusses locking tabs or barbs protruding from two levels of the locking ring to engage locking recesses on the inner surface of the metal shell. The locking ring must be of a deformable material to allow for insertion of the femoral head. The Huebner patent refers to the inventive structure therein as providing a "dual locking mechanism for locking the component assembly". Thus, considering Huebner in its entirety, as is required under 35 USC § 103, one of ordinary skill in the art would not be motivated to use a ceramic insert for a taper-lock construction. It is noted that a ceramic is mentioned in column 5 at about lines 46 to 52 as a material which is relatively inert, has low friction, and is smooth. However, Huebner does not use a taper-lock and requires the locking ring 10. Thus, Huebner cannot be properly combined with Noiles or with Cremascoli.

The angle in Huebner is about 40° and therefore it is in a range in which no sufficient locking would occur, even in a ceramic-to-metal joint.

The Lewis patent is concerned with the use of spacers (40) on the outer surface of the outer shell. In Figure 5, and in column 4 starting at about line 32, there is a discussion of a ceramic inner liner. However, Lewis does not show or suggest a taper-lock construction. Further, there is not the slightest suggestion in Lewis that liner (28) is removable.

It is submitted that none of the references alone or in combination show or suggest the now claimed subject matter. In the Cremascoli structure, the ceramic cannot be removed from the structure without destruction of that part of the prosthesis since it is cast into the outer metal annular body. Thus, Cremascoli does not show or suggest a salient feature of the now claimed invention, i.e., the ceramic anti-friction liner is removably fixed in the metal shell. As explained in the present specification, the anti-friction liner is removably fixed in such a manner that its removal does not require the destruction of the ceramic liner or the metal shell.

Further, the layered coating of granular material must be firmly attached to the outer surface of the ceramic portion of Cremascoli's structure. Clearly the granular material is not removable from the structure. More telling is the fact that the granular material serves to permit adequate bone re-growth between the interstices of the granular layer for anchorage. Since the granular layer is thus anchored to bone or by its outer surface and non-removably fixed to the ceramic portion 5 on its inner most layer, it is clear that Cremascoli does not contemplate or suggest a non-destructive removability feature as recited in the pending claims (see claim 1).

Further, the Huebner construction requires a locking ring and does not employ a taper-lock. Further, it is clear from the Huebner reference that the locking ring is an important part of the invention and is described in significant detail. In fact, the description of the locking ring includes more than 10 lines of the broadest claim of Huebner. The Examiner is not free to disregard such a salient feature of a prior art reference which is obviously an important part of Huebner's invention. Likewise, in the Lewis structure, the spacers 40 are an important feature of the invention disclosed therein.

It is submitted that the combination of references is improper and is the product of hindsight reconstruction and fails to consider the references in their entirety. It is clear from the intricate machining required for the bearing 13 of Noiles that such an element cannot be made of ceramic. Further, the ceramic portion of the Cremascoli structure is part of the external shell (see Figure 1) and is formed so as to be non-removable. The combination of these references would be contrary to one another since each discloses a different element for a different purpose to obtain a different result. Further, it is an improper combination of references where one or more of the references is modified to a form which would render it inoperable for its intended purpose, see Ex parte Hartmann, 186 U.S.P.Q. 366, 367 (POBA, 1974) or changes the basic principles on which the invention of the reference operates, see In re Ratti, 123 U.S.P.Q. 349 (CCPA, 1959).

Clearly, the rejection is the product of hindsight reconstruction. The art does not provide motivation for the combination. Even where separate elements are shown in the art, such does not provide motivation for a combination even when the references are from the same art, In re Levitt, 11 U.S.P.Q. 1315 (Fed. Cir., 1989) (Unpub.). Further, the rejection does not state any specific motivation provided by the cited references for the combination. As such, the rejection is improper as a matter of law. See In re Laskowski, 10 U.S.P.Q. 2d 1397 (Fed. Cir., 1989) and In re Grabiak, 226 U.S.P.Q. 870, 872 (Fed. Cir., 1985). Specific motivation is required. See In re Deuel, 34 U.S.P.Q. 2d 1210, 1216 (Fed. Cir., 1995).

The Examiner is again requested to acknowledge the Information Disclosure Statement filed on or about April 27, 1995 and which apparently crossed in the mail with Paper No. 3.

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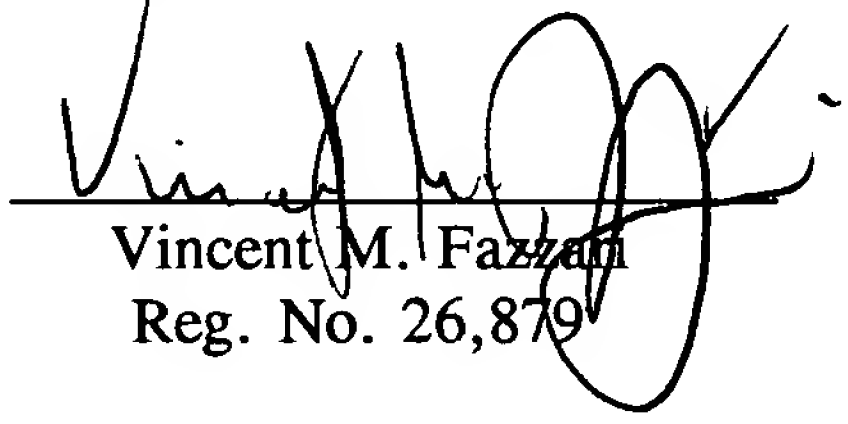
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In view of the foregoing, reconsideration and allowance of the application with claims 1 to 4 and 8 are earnestly solicited.

Respectfully submitted,

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Enclosure(s): One-Month Extension of Time

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